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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,366

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Michele Orlando

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EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

03/11/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/506,366	Applicant(s) ORLANDO ET AL.	
	Examiner EVERETT WHITE	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 15, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-78 is/are pending in the application.
- 4a) Of the above claim(s) 57-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-56 and 74-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/15/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The reply filed December 15, 2008 has been received, entered and carefully considered. The reply affects the instant application accordingly:

- (A) Claims 1-36 were previously canceled;
- (B) Comments regarding Office Action have been provided drawn to:
 - (I) 102(b) rejections, which have been maintained for the reasons of record;
 - (II) 103(a) rejection, which is maintained for the reasons of record.

2. Claims 37-78 are pending in the case; Claims 57-73 are withdrawn from consideration as being directed to non-elected inventions.

Foreign Priority Claimed

3. This application is a 371 of PCT/EP03/02084 International Filing Date: February 28, 2003 published in German, which claims foreign priority to Germany 10209822.0 under 35 U.S.C. 119(a)-(d). It is noted that PCT/EP03/02084 and Germany 10209822.0 (March 6, 2002) are in German, no translation of the documents into English has been provided.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 37-45, 47, 48, 50, 52, 56 and 74-78 stand rejected under 35 U.S.C. 102(b) as being anticipated by Adamson (CA 2233725 A1) for the reasons disclosed on pages 2 and 3 of the Office Action filed June 13, 2008.

6. Applicant's arguments filed December 15, 2008 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the instant claims recite conjugates being formed via the terminal aldehyde group of the hydroxyalkylstarch wherein the Adamson publication discloses the hydroxyalkylstarch

being modified with aldehyde groups at different positions of the hydroxyalkylstarch molecule. This argument is not persuasive since there is no indication in the Adamson publication that aldehyde groups are not formed on the terminal unit of the hydroxyalkylstarch. Furthermore, the instant specification does not clearly define the phrase "terminal aldehyde group of the hydroxyalkylstarch molecule". That is, it is not clear in the claims and specification that the phrase is in reference to an aldehyde group being formed on the terminal saccharide unit of the hydroxyalkylstarch.

Applicants also argue that the Adamson publication does not disclose conjugating a low molecular weight substance to the hydroxyethylstarch thereof. This argument is not persuasive since the molecular weight of the "substance" disclosed in the instant claims has not been recited in the claims.

Accordingly, the rejection of Claims 37-45, 47, 48, 50, 52, 56 and 74-78 under 35 U.S.C. 102(b) as being anticipated by the Adamson publication is maintained for the reasons of record.

7. Claims 37-45, 47-56 and 74-78 stand rejected under 35 U.S.C. 102(b) as being anticipated by Harboe et al (EP 331471 A) for the reasons disclosed on pages 3 and 4 of the Office Action filed June 13, 2008.

8. Applicant's arguments filed December 15, 2008 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the Harboe et al publication discloses that the conjugate is formed by reacting free hydroxyl groups of the hydroxyalkylstarch with the functional group of the drug as opposed to reacting an aldehyde group of the hydroxyalkylstarch with the drug. This argument is not persuasive since the "A" symbol in the formula of the Harboe et al publication may be represented as a "CO" group which would meet the requirement of the instantly claimed conjugate being anticipated by the anti-inflammatory formula of the Harboe et al publication. Applicants are reminded that process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), supra; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall*

Containers, Inc. v. United States et al. (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981.

Accordingly, the rejection of Claims 37-45, 47-56 and 74-78 under 35 U.S.C. 102(b) as being anticipated by the Harboe et al publication is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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10. Claims 37-45, 47-56 and 74-78 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Adamson (CA 2233725 A1) or Harboe et al (EP 331471 A) or Berger et al (EP 019403 A2) in view of Weidler et al (US Patent No. 5,502,043) for the reasons disclosed on pages 5 and 7 of the Office Action filed June 13, 2008.

11. Applicant's arguments filed December 15, 2008 have been fully considered but they are not persuasive. The response to the arguments presented above against the Adamson and Harboe et al publications in the 102(b) rejections can be presented herein for the 103(a) rejection. Applicants argue against the rejection on the ground that the Berger et al publication does not disclose coupling a low molecular weight substance to the terminal aldehyde group of the hydroxyalkylstarch. This argument is not persuasive since there is no indication in the Berger et al publication that aldehyde groups are not formed on the terminal unit of the hydroxyalkyl-starch. Furthermore, the instant specification does not clearly define the phrase "terminal aldehyde group of the hydroxyalkylstarch molecule". That is, it is not clear in the claims and specification that the phrase is in reference to an aldehyde group being formed on the terminal saccharide unit of the hydroxyalkylstarch.

The Weidler et al patent is only disclosed to show that the instantly claimed range of the C_2 / C_6 ratio of a hydroxyalkyl starch being 8 to 12 is known in the art.

Accordingly, the rejection of Claims 37-45, 47-56 and 74-78 under 35 U.S.C. 103(a) as being unpatentable over the Adamson or Harboe et al or Berger et al publication in view of the Weidler et al patent is maintained for the reasons of record.

Summary

12. Claims 37-56 and 74-78 are rejected; Claims 57-73 are withdrawn from consideration as being directed to non-elected inventions.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623